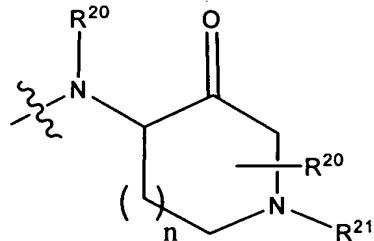


REMARKS

The Requirement for Restriction

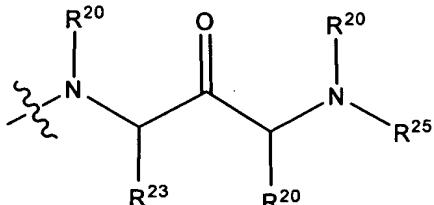
The Action requires applicants to select one of the following three groups of allegedly patentably distinct inventions for examination.

I. Claims 1 to 16, drawn to compounds and compositions according to Formula I, wherein X³ is a group of formula (a) which has the following structure.



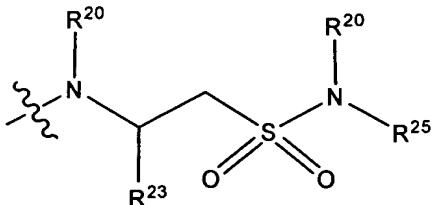
(a)

II. Claims 1 to 16, drawn to compounds and compositions according to Formula I, wherein X³ is a group of formula (b) which has the following structure.



(b)

III. Claims 1 to 16, drawn to compounds and compositions according to Formula I, wherein X³ is a group of formula (c) which has the following structure.



(c)

Regarding groups I to III, the Action acknowledges that claim 1 is in a "Markush group" format, but asserts that the members of the group do not possess unity of invention and instead are "patentably distinct inventions" because each member shares in common only a sulfonyl-alkyl-amine backbone which is not considered by the Examiner as constituting a substantial structural feature (Action, page 3).

The Action alleges also that patentably distinct species exist within the above-identified groups and has required that applicants elect a species from within the elected group (Action, page 2).

Traversal of Restriction Requirement and Election of Species

Applicants submit respectfully that the Examiner's requirement for restriction and election of species (hereinafter "requirement/election") are improper in that they

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are in contravention to Patent Office policy as set forth in MPEP § 803.02 and the case law.

Traversal Based on MPEP § 803.02 Considerations

Patent Office policy, as set for in MPEP § 803.02, provides that there is no basis for a restriction/election of a Markush claimed invention where two factors are met, *i.e.*,

... compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicants' claimed invention meets the aforesaid factors. As detailed below, the enhancers not only share a *common utility*, but also share a *substantial structural feature* that is essential to that utility.

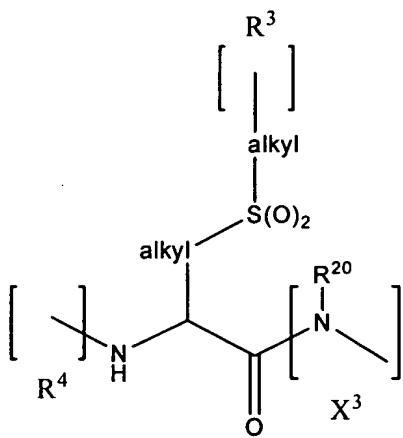
Regarding the first factor, *i.e.*, common utility, the Action does not dispute that all of the compounds share the same utility, that is, to inhibit the activity of cathepsin S. Accordingly, applicants' claimed invention meets the aforementioned first factor.

Regarding the second factor, *i.e.*, substantial structural feature being essential to the utility, the Action acknowledges that there is a structural feature common to all members of the above-identified groups, but concludes that this common structural feature is not a substantial structural feature. This statement is factually incorrect. As

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detailed below, there indeed is a substantial structural feature that is common to all of the members of the above-identified groups, namely, that portion of the compound to which the pendant group X^3 is attached and which is referred to hereinafter as "the backbone". The backbone comprises a substantial portion of the compounds of the present application, as is abundantly clear from the structure set forth below.



The Action does not include any information respecting evidence or technical reasoning to support the position that this shared and substantial backbone of the claimed compounds is *not* essential to the utility of the claimed compounds.

It is well established that the Action must include reasons and/or examples to support conclusions which are expressed in the Action (MPEP § 803). The Action is, however, silent on this requirement and includes a conclusion based on presumption, the truth of which has not been shown.

In sum, the two-prong test of MPEP § 803.02 is satisfied by applicants' claims. The Examiner does not dispute that all of the claimed compounds share the same utility

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and that the compounds represented by the claims of Groups I to III share a substantial structural feature that is essential to that utility. Significantly, the Action provides no evidence or technical reasoning to the contrary. Accordingly, the restriction requirement is improper and should be withdrawn.

Traversal Based on Case Law Considerations

As detailed below, well-settled case law such as, for example, *In re Harnisch*, 206 U.S.P.Q. 300 (CCPA 1980) and *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208 (Bd. App., 1938), supports applicants' position that the present restriction/election requirement is improper because, as stated above, the Action has concluded erroneously that the inhibitors of applicants' claimed invention do not share a distinct structural feature linked to a particular function.

For example, in *In re Harnisch*, 206 U.S.P.Q. 300, 305 (CCPA 1980), the court found that an invention claimed in a Markush type claim was proper for compounds having a common utility and "*a single structural similarity*" (emphasis added). In particular, in agreeing with its earlier decisions, the court stated that a Markush group was proper where there is a

grouping of compounds having the *same nuclei but side chains wherein there was a wide variation ... and had a community of properties justifying their grouping* (emphasis added).

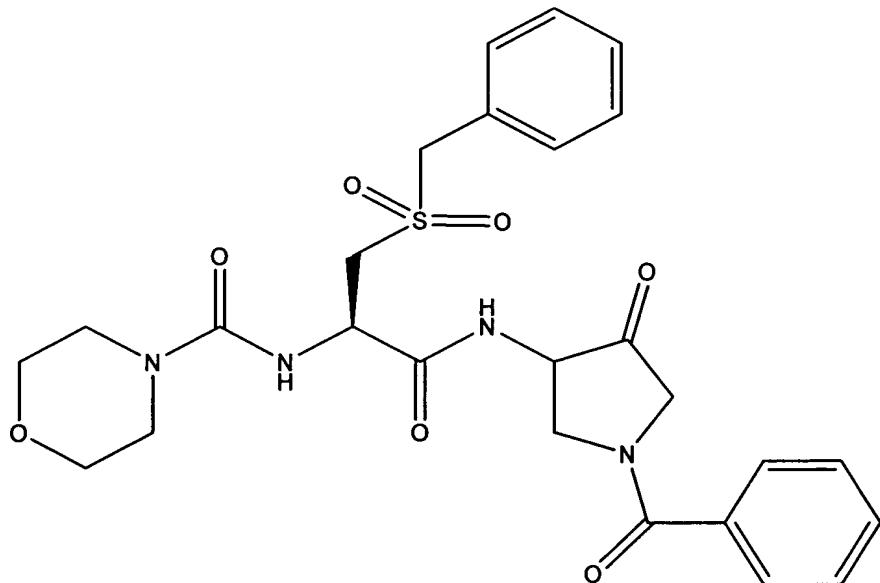
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The Court held that, when such criteria exist, there is unity of invention within the claimed Markush group. *Id.* Significantly, applicants' claimed compounds have the same backbone which is a significant portion of the compounds, pendant groups defining a variety of structures, and the common property of cathepsin S inhibition; accordingly, the claimed compounds meet the standard of *In re Harnisch*. Therefore, there is no propriety for the present restriction/election and reconsideration and withdrawal of the election/restriction requirement are requested respectfully.

Provisional Election

Although applicants submit respectfully that the imposed species restriction/election is improper, applicants elect provisionally Group I for prosecution along with the species



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which is the subject of Example 1 in the present application.

Applicants confirm the right to pursue the patenting in a divisional application of any subject matter that remains after prosecution of the present application.

Conclusion

The Examiner is requested to call the undersigned at the telephone number listed below to discuss any matter that may accelerate prosecution.

Respectfully submitted,



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